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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,577	06/28/2001	Shigefumi Sakai	210354US0	2545

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/892,577

Applicant(s)

SAKAI ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,3 and 20-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3, and 20-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

Receipt is acknowledged of Amendment filed on July 18, 2002. Claims 2, 3, 20-32 are pending. Claim rejections indicated in the Office action dated March 18, 2002 are withdrawn in view of applicants' claim amendment. New rejections are made in view of the amendment and new claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, and 20-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20 recites hydrogel particles having oil component "being dispersed" therein. While the original disclosure supports oil component *contained* in the hydrogel particles, there is no support for the dispersion of the oil components in the hydrogel particles.

Claim 25 recites a composition wherein "not less than 80 % by weight" of the hydrogel particles therein have "a ratio of a longest diameter to a shortest diameter (longest diameter/shortest diameter) of not more than 1.7." There is no support for this limitation in the original disclosure.

The remaining claims are rejected as depending on claims that are not supported by original disclosure.

***Claim Rejections - 35 USC § 112***

Claims 22 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “macromolecular emulsifying or dispersing agent” renders claim 22 vague and indefinite, as the metes and bounds of the scope of the claim is unclear.

Claim 25 is vague and indefinite as it is not clear whether the claim limitation is concerned with the particle size distribution in the composition or the uniformity of the shape of each hydrogel particle.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 2, 3, and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsaur et al. (US 5726138) (“Tsaur”).

Tsaur discloses aqueous compositions comprising hydrogel particles comprising water-insoluble skin benefit ingredients entrapped therein. See col. 2, line 63 – col. 3, line 60. The reference teaches that the benefit agent is dispersed in the hydrogel-forming polymers before the formation into hydrogel particles. See col. 4, lines 28 – 44; instant claim 2. Using surfactants in mixing the benefit agent and the hydrogel-forming polymer solution is also disclosed in col. 9, lines 6 – 24. Cocoamido propylbetaine,

which is considered a “macromolecular” emulsifying agent, is used in Example 6. See instant claim 22. The reference teaches an aqueous lotion composition with petrolatum, a solid fatty substance, contained in a hydrogel particle comprising chitosan, a non-crosslinked, thermal gelatin. See Example 15; instant claims 20, 23, and 28. The diameter of the petrolatum hydrogel particles there is deemed to be 200 microns. See instant claim 29. See also col. 3, lines 28 – 32, which teaches that the diameter of the particles should be greater than 25 microns.

Tsaur teaches to use two types of polymers to form hydrogel, wherein the first polymer may be thermal gelatin, such as agar or gelatins; and the second polymer is selected depending on the desired gel strength. See col. 5, line 56 – col. 6, line 22; instant claims 3. The reference further teaches that the gel strength can be manipulated by controlling the amounts of the two polymers and the particle size. See col. 7, lines 33 – 40; col. 17, lines 44 – 57; instant claims 26, 27, and 30. See also col. 3, lines 4 – 27 for the weight amount of the hydrogel composition. See instant claim 31.

The amount of the benefit agent in the hydrogel polymer solution is said to be in the range of 5 – 65 % by weight. See col. 9, lines 15 – 24. Tsaur also teaches that the suitable benefit agents include waxes, ceramides, and pseudoceramides. See col. 8, lines 5 – 58; Examples 8-10; see instant claims 23 and 24. The reference also teaches that in case of a liquid cleanser, the typical pH is in the range of 5-7. See instant claim 32.

Examiner interprets the limitation on the particle size ratio claim 25 to mean that more than or equal to 80 % of the hydrogel gel particles have substantially spherical

shape, so that the ratio of the longest diameter/shortest diameter of a single gel particle is less than or equal to 1.7. While the Tsaur reference does not explicitly teach the recited ratio of the instant claim, examiner notes that that the reference teaches a single value of gel sizes measured for each illustrated formulation. See, for example, Table 12. Examiner takes the position that the prior art hydrogel particles are in substantially uniform shape, thus meeting the instant claim limitation.

While the Tsaur reference fails to illustrate a hydrogel particle formed with agar or gelatin, as in instant claim 3, examiner notes that it is prima facie obvious to substitute equivalents known for the same purposes so long as the equivalency is recognized in the prior arts. See MPEP § 2144.06.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the illustrated inventions in Tsaur by substituting the hydrogel polymers used there with another conventional gelling agent such as agar and/or gelatin as motivated by the teachings therein because of the expectation of successfully producing a similar composition.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

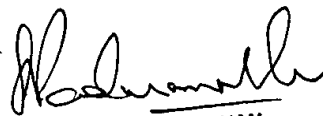
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
October 19, 2002

  
SREENI PADMANABHAN  
PRIMARY EXAMINER 10/21/02